

to compare two large commercial databases focusing on CHC patient characteristics and treatment patterns. **METHODS:** We analyzed the Japan Medical Data Center (JMDC) database containing employer-based health insurance claims and the Medical Data Vision (MDV) database containing administrative data from acute care hospitals. Patients aged 20 years or above and diagnosed with CHC were included in the study. Patients co-infected with hepatitis B and/or human immunodeficiency viruses were excluded. Patient characteristics and treatment patterns for CHC were compared. **RESULTS:** 3,590 (JMDC) and 29,702 (MDV) confirmed CHC patients were included in the analysis. Patients in JMDC were younger than those in MDV (age 51.6±11.9 and 63.2±13.4) and had fewer comorbidities (Charlson Comorbidity Index 1.3±1.7 and 1.9±2.1). More patients in JMDC were found to have prior CHC treatment (37.2%) than in MDV (24.6%). With an index date of September 2011, about a third of the patients (n=1,271, 35.4%; JMDC and n=9,791, 33.0%; MDV) received treatments for CHC, comprised of 10.2% (n=365; JMDC) and 5.5% (n=1,620; MDV) on antiviral treatments (interferon or direct acting antiviral combinations) and 25.2% (n=906; JMDC) and 27.5% (n=8,171; MDV) on liver protection drugs only. Among patients treated with triple therapy (telaprevir/peginterferon/ribavirin), the mean total treatment duration was 19.3 weeks (JMDC) versus 21.9 weeks (MDV). The mean duration of telaprevir therapy was 10.8 weeks (JMDC) and 10.1 weeks (MDV), followed by 11.7 weeks (JMDC) and 14.1 weeks (MDV) of peginterferon/ribavirin therapy. **CONCLUSIONS:** Both databases found low treatment rates for CHC. Although the findings are consistent, there are differences in database populations and treatment patterns that warrant further research. Using these administrative databases for real-world research may be useful depending on research objectives.

PGI47

COHORT OF HCV PATIENTS IN ITALY: SIZING AND TREATMENTS IN A SAMPLE OF ITALIAN HEPATOLOGY CENTERS

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OBJECTIVES: The aim of this study is to give an overview of the treatment available for the patients with Hepatitis C Virus (HCV) through the segmentation of HCV patients in Italy. **METHODS:** The study was carried out in 9 hepatology centers, treating HCV patients in 9 Italian Regions. The structures selected constitute a representative sample of the Italian scenario, being Centers of Excellence in HCV management in northern, southern, and center of Italy (representing about 24% of the 2.000 patients treated with first generation Triple Therapy in Italy according to AIFA Data). The patients' distribution has been investigated in terms of fibrosis stage (F0 to F4), therapy type (Triple, TT, or Double therapy, DT) and treatment status (naïve or experienced patients). **RESULTS:** Data (collected from structures and Workshop of Pharmacoeconomics in Hepatology) show that HCV patients are more concentrated in the two fibrosis stage extremes: 43% in F0-F1 Range, 23% in F2, 32% in F3-F4 Range and 2% unclassified. Data about drug administration demonstrate that, at national level, patients are equally distributed between therapy type (56% TT and 44% DT) and treatment status (49% naïve and 51% experienced). On the contrary, at Regional level many differences were found in all of the three parameters examined. In the structure investigated in Campania, for example, 72% of patients receive TT and 76% are experienced, while in Lazio 72% of patients receive DT and 72% are naïve. Furthermore, considering the fibrosis stage, the 46% of patients treated in a center operating in Bari is in the range F3-F4, whilst in the center in Milan the 56% of the HCV patients treated is in range F0-F1. **CONCLUSIONS:** The study demonstrate that, concerning the treatment of HCV, there are significant differences among the hepatology centers, both in terms of patients' health status and therapy pathways.

PGI48

THE COSTS-EFFECTIVENESS OF SOFOSBUVIR VERSUS STANDARD OF CARE (SOC) IN CHRONIC HEPATITIS C FROM A BELGIAN REIMBURSEMENT PERSPECTIVE

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OBJECTIVES: Hepatitis C virus (HCV) infection resulting in chronic liver disease has an estimated prevalence in Belgium of 0.87% (Beutels, 1997) with 59% of patients having genotype 1 HCV (GT1), 6% GT2, 19% GT3 and 16% GT4-5-6. Sofosbuvir (SOF), a novel HCV treatment, has demonstrated high rates of sustained virological response (SVR) when given with ribavirin to subjects with chronic HCV infections (all GTs). The objective of this analysis was to assess the cost-effectiveness of sofosbuvir vs SoC in the treatment of chronic hepatitis C (CHC) in the following indications: GT 1 (Treatment Naïve (TN), INF-eligible and IFN-ineligible patients); GT2 & 3 (TN & Treatment Experienced (TE), both INF-eligible and IFN-ineligible patients) and GT 4/5/6, treatment-naïve patients in Belgium. Patients ineligible to IFN have no treatment options today. **METHODS:** Based on a Markov model, this cost-utility analysis models the cost-effectiveness of SOF versus SoC in Belgium from the perspective of the RIZIV/INAMI and taking into account the proposed reimbursement criteria for SOF in Belgium and the guidelines of the Knowledge Centre (KCE) (KCE report 78C, 2008). **RESULTS:** Weighted ICERs were calculated taking into account patient eligibility for treatment with IFN and treatment duration with SOF: GT 1, 3, 4, 5 or 6 patients who are IFN-eligible and are being treated with SOF (+ subcutaneous pegylated interferon-alpha (IFN-α) plus daily oral ribavirin (RBV)) for 12 weeks (€19,954/QALY); GT 1, 3, 4, 5 or 6 patients who are IFN-ineligible due to intolerance and/or contra-indications and are being treated with SOF (+ RBV) for 24 weeks (€35,086/QALY) and GT 2 patients that are being treated with SOF (+ RBV) for 12 weeks (€28,121/QALY). Overall, the weighted PAN-genotypic ICER was €21,651. **CONCLUSIONS:** PAN-genotypic cost-effectiveness has been demonstrated for sofosbuvir in comparison to the current standard of care in HCV in Belgium.

PGI49

WHICH METRIC TO CHOOSE FOR INDIRECT COMPARISON OF TREATMENTS WHEN MULTIPLE COMPARISONS ARE FEASIBLE: LUBIPROSTONE VERSUS PRUCALOPRIDE IN CHRONIC CONSTIPATION

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OBJECTIVES: For a recent health technology appraisal in the treatment of chronic idiopathic constipation, direct evidence of the effectiveness of a new intervention (lubiprostone) against the standard of care (prucalopride) was not available. The aim of this study was to review the available data from clinical trials and perform indirect comparisons between the two treatments where possible. **METHODS:** A literature search (in Medline and other databases) was conducted in December 2013 for trials of lubiprostone or prucalopride. Data for any comparable endpoints were extracted from the papers, and indirect comparisons performed using the Bucher method. **RESULTS:** Four clinical trials for lubiprostone were identified (three company-sponsored, and a small clinician-led trial), as well as three company-sponsored clinical trials for prucalopride. After data extraction, indirect comparisons were possible for seven different endpoints, including the primary efficacy parameter of the lubiprostone studies (Spontaneous Bowel Movements; the relative risk was 1.12 in favour of lubiprostone, 95% CI 0.77-1.64). Other endpoints included the primary efficacy parameter of the prucalopride studies (Spontaneous Complete Bowel Movements), and a range of symptom comparisons. In total, five of the seven indirect comparisons favoured lubiprostone, with statistical significance reached in favour of lubiprostone once and prucalopride once. **CONCLUSIONS:** The indirect comparisons showed that lubiprostone is likely to be at least as effective as prucalopride, with numerical superiority in five out of seven comparisons. However, the number of feasible indirect comparisons on a range of endpoints raises a wider question: which to use in cost-effectiveness modelling? Although analyses generally have a 'base case', each of the indirect comparisons adds different information about the relative efficacy of the two products. Given the range of endpoints with associated relative risks, to reduce these to a single comparison (as is current practice) may omit important and relevant information about relative efficacy.

PGI50

HIGH THERAPEUTIC EFFICIENCY WITH SOFOSBUVIR FOR THE TREATMENT OF CHRONIC HEPATITIS C

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OBJECTIVES: Chronic hepatitis C (CHC) is a major public health problem contributing to more than 86,000 premature deaths in Europe. Pegylated interferon-α plus ribavirin (PR) based therapy, including regimens with boceprevir (BOC) or telaprevir (TVR) in HCV genotype-1 patients, have failed to provide more extensive therapeutic benefit leaving space for substantial outcomes improvement. Sofosbuvir (SOF) – a pan-genotypic RNA polymerase inhibitor – has shown unprecedented sustained virologic response rates and tolerability profiles. The objective of this study was to estimate SOF contribution to public health by exhausting CHC therapeutic efficiency. **METHODS:** Therapeutic efficiency was defined as maximum capacity to benefit from treatment in terms of life years (LY) relative to the general population's life expectancy. The natural history of CHC and treatment implication was modelled with a discrete-time Markov allowing for long term assessment in terms of HCV genotype, fibrosis progression, HIV co-infection status and previous treatment experience. Treatment options compared were dependent on interferon eligibility/tolerance and genotype: PR, SOF/PR, BOC/PR and TVR/PR in eligible/tolerant patients (BOC/TRV regimens in genotype-1 only; SOF/ribavirin in genotype-2). For ineligible/intolerant patients, comparison of SOF/ribavirin was performed against lack-of-therapy. **RESULTS:** In mono-infected HCV genotype-1 patients SOF/PR treatment is estimated to result in 4.3 LY, 7.0 LY or 8.0 LY gained in comparison to TRV/PR, BOC/PR or PR, respectively. In genotype-1 and genotype-2 HIV-coinfected patients eligible for interferon treatment, the estimated LY gained with SOF treatment is 11.8yrs and 5.0yrs, respectively. In patients ineligible for interferon treatment, SOF is expected to almost double life expectancy irrespective of the genotype, with therapeutic efficiency ranging from 79% to 95%. In co-infected patients, therapeutic efficiency of SOF is expected to range between 84.3% and 92.4% of general population life expectancy. **CONCLUSIONS:** Sofosbuvir-containing regimens are expected to maximize years of life lived and maximize efficiency relative CHC patients residual life expectancy.

PGI52

COMPARISON OF THE BURDEN OF IBS WITH CONSTIPATION ON HEALTH-RELATED QUALITY OF LIFE (HRQOL), WORK PRODUCTIVITY, AND HEALTH CARE UTILIZATION TO ASTHMA, MIGRAINE, AND RHEUMATOID ARTHRITIS IN THE US, UK, AND FRANCE

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OBJECTIVES: Studies have shown that irritable bowel syndrome (IBS) and its subtype with constipation (IBS-C) are associated with poorer HRQOL, decreased work productivity and increased health care utilization. However, no studies have compared the burden of IBS-C to similar chronic conditions. Objective was to evaluate burden of IBS-C compared with no functional gastrointestinal disorders (non-FGID), asthma, migraine, and rheumatoid arthritis (RA), on HRQOL, work productivity and health care utilization. **METHODS:** Data come from the 2011 National Health and Wellness Survey (nationally representative sample of adults including the US, UK and France), which includes health-related topics such as HRQOL (SF-12 Health Survey), work productivity (Work Productivity and Activity Impairment) and health care utilization.